Exhibit IX

FDA Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 22 1999

NADA 140-863, E0076

Bruce W. Martin, DVM, Ph.D.
Manager, Animal Science Regulatory Affairs
Elanco Animal Health
2001 W. Main Street
P.O. Box 708
Greenfield, IN 46140

Dear Dr. Martin:

We refer to your letter dated October 8, 1999, which reactivated your original new animal drug application on (NADA 140-863) for the use of ractopamine hydrochloride in finishing swine feeds. We also refer to your letters dated October 12, November 3, and December 12, 1999, that contained final Copies of the Type A medicated article label and Type B and C medicated feed labels as well as the missing pages from your environmental assessment and corrected patent information. These submissions fulfill the requirements for approval of your original NADA for ractopamine hydrochloride (Paylean®) in finishing swine.

We have completed our review of your new animal drug application and find that it supports the approval of ractopamine hydrochloride (Paylean®) in finishing swine for increased rate of weight gain, improved feed efficiency, and increased carcass leanness when fed at 4.5 g ractopamine hydrochloride/ton of feed when swine are fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight, and for improved feed efficiency and increased carcass leanness when fed at 4.5 to 18 g ractopamine hydrochloride/ton of feed when swine are fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight. Further, a zero-day withdrawal period is approved for the indications listed above. A copy of the Freedom of Information Summary is enclosed for your files.

The application is approved as of the date of this letter. You may initiate distribution and marketing of this product upon completion of manufacturing process validation and after submitting three (3) copies of each component of the final printed labeling (FPL).

The FPL should be submitted under separate cover directly to:

Document Control Unit (UFV- 199)
Attention: HFV- 120
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

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The stability data submitted with this application supports a 24 months expiration date for the Paylean® Type A medicated article. A 24 months expiration date should be placed on the labeling for the drug product. Labeling must be identical to the labeling submitted in your application.

Although the completion of manufacturing process validation is not a requirement for pre-approval, it is a cGMP requirement that must be met before any shipments of drug product are made. Manufacturing process validation is based on the documented successful evaluation of multiple full scale batches (usually a minimum of three (3)) and provides assurance that the processes will reliably meet predetermined specifications. This information may have been available for evaluation by the FDA District Office during the pre-approval inspection and may have been found acceptable, However, if this information was not available at that time or process validation deficiencies were noted by the FDA Investigator during the pre-approval inspection, the appropriate FDA District Office should be contacted after manufacturing process validation has been completed and prior to shipment of the drug product. This will provide (he FDA District Office the opportunity to inspect and verify the validation of the manufacturing process. Regulatory action, such as seizure, will be considered in instances where there is shipment of the drug product prior to completion of the process validation.

Under section 512(cX2)(F)(i) of the FFDCA, this approval qualifies for FIVE years of marketing exclusivity beginning on the date of approval because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application.

Future correspondence regarding this approval should reference the correspondence date of this submission and our file number, NADA 140-863, E0076. Any request to change the conditions of the original approval for this NADA will be considered a supplement to your original NADA.

Sincerely yours,

signed

Stephen F. Sundlof, DVM, Ph.D.
Director, Center for Veterinary Medicine

Enclosure (FOI Summary)